SUPPORTING STATEMENT − OMB NO. 0579-0256
Export Health Certificate for Animal Products

TERMS OF CLEARANCE: OMB notes that this collection includes certification that animal products are free of rinderpest, as well as other diseases. Recent reports indicate that rinderpest may have been successfully eliminated. Upon submission of this collection for reapproval, APHIS should consider removing the requirements for certification of these animal products as free of rinderpest, if the agency determines that this is appropriate.

APHIS believes pockets of the disease may still exist in sub-saharan Africa. While APHIS does not know that for sure, it is not prepared to recognize the entire world as free.

A. JUSTIFICATION August 2013

"Export Health Certificate for Animal Products" is the present title for this collection. Previously, it was "Health Certificate/Export Certificate-Animal Products."

1. Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitate the collection. Attach a copy of the appropriate section of each statute and regulation mandating or authorizing the collection of information.

The Animal Health Protection Act (AHPA) of 2002 is the primary Federal law governing the protection of animal health. The law gives the Secretary of Agriculture broad authority to detect, control, or eradicate pests or diseases of livestock or poultry. The Secretary may also prohibit or restrict import or export of any animal or related material if necessary to prevent the spread of any livestock or poultry pest or disease. The AHPA is contained in title X, subtitle E, sections 10401-18 of P.L. 107·171, May 13, 2002, the Farm Security and Rural Investment Act of 2002.

The export of agricultural commodities, including animals and animal products, is a major business in the United States and contributes to a favorable balance of trade. As part of its mission to facilitate the export of United States animals and products, the United States Department of Agriculture (USDA), Animal and Plant Health inspection Service (APHIS), Veterinary Services (VS), maintains information regarding the import health requirements of other countries for animals and animal products exported from the United States.

Many countries that import animal products from the United States require a certification that the United States is free of certain diseases. These countries may also require that APHIS' certification statement contain additional declarations regarding the United States animal products being exported. This certification must generally carry the USDA seal and be endorsed by a Federal veterinarian.

VS Form 16-4, Health/Export Certificate-Animal Products, and VS Form 16-4A, Health/Export Certificate-Animal Products Continuation Sheet, a hearing request to appeal VS' decision to refuse to grant a certificate, and a Notification of Tampered Certificate can be used to meet these requirements.

The regulations governing the export of animal products from the United States are found in subchapter D, part 91 of title 9 of the *Code of Federal Regulations* (9 CFR): Exportation and Importation of Animals (Including Poultry) and Animal Products. These regulations are authorized by 21 U.S.C. 117, the Animal Industry Act.

APHIS is asking OMB to approve its use of VS 16-4, VS l6-4A, Hearing Request, and Notification of Tampered Certificate, in connection with its efforts to address the animal product import requirements of other countries.

2. Indicate how, by whom, how frequently, and for what purpose the information is to be used. Except for a new collection, indicate the actual use the agency has made of the information received from the current collection.

APHIS uses the following information activities to regulate the governing of the export of animal products from the United States.

Export Certificate for Animal Products (VS 16-4) - Business
The VS 16-4 serves as USDA's official certification that the United States is free of rinderpest, foot-and-mouth disease, classical swine fever, swine vesicular disease, African swine fever, bovine fever, bovine spongiform encephalopathy, and contagious bovine pleuropneumonia.

A United States exporter wishing to export animal products to another country must complete a section of the VS 16-4 entitled "Description of the Consignment." The form captures the exporter's name and address; the name and address of the consignee; the quantity, unit of measure, and type of product being exported; the exporter's identification; and the type of conveyance (ship, train, truck) that will transport the products. The form also asks for any declarations the receiving country might require, such as statements concerning where the product originated and how it was processed.

Once the form is completed, the exporter submits the VS 16-4 to VS, which reviews the form for completeness and accuracy before the authorized Federal veterinarian (endorsing official) signs it. The VS 16-4 remains valid for 30 days after the date of signature.

Export Certificate for Animal Products Continuation Sheet (VS 16-4A) - Business
For the United States exporters who are exporting numerous products, the VS 16-4 does not provide adequate space for the information the importing country has requested. VS uses a continuation sheet, the VS 16-4A, to provide the additional space some exporters need to complete the VS 16-4. Besides the space for the continuation of information, there is a confirmation block. The exporter fills in the additional information, and VS completes the information about the certificate number, the page number, and initials the form.

Hearing Request - Business
VS may refuse to grant a certificate to an exporter (9 CFR 156.8) if that exporter fails to meet conditions set forth in 9 CFR 156.5 and 156.6. If VS refuses to grant a certificate, the exporter may request a hearing to appeal the decision.

Notification of Tampered Certificate - Business
VS may issue a denial or withdrawal of service if it determines that a certificate VS has issued has been altered or if parts of the certificate or its marks or devices have been imitated, or that the
recipient of the official certificate, mark, or device has used it without authority from the Administrator. An exporter who has been issued a denial or withdrawal of service can appeal this ruling.

Exporters can request either a hearing to appeal a denial of a certificate, or notification of a tampered certificate, by mail or phone to the USDA's Office of General Counsel (OGC). Exporters can find contact information for OGC's regional offices and staff on the USDA website at: http://www.usda.gov/wps/portal/usda?navid=OGC.

3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses, and the basis for the decision for adopting this means of collection. Also describe any consideration of using information technology to reduce burden.

The VS 16-4 and 16-4A are available as electronic forms. Exporters can download the VS 16-4 and l6-4A, complete the appropriate sections, print out the forms if they choose, and submit them to VS via email, fax, or mail. The VS staff then reviews this information and provides a hard copy for the export veterinarian to sign.

Exporters can request either a hearing to appeal a denial of a certificate, or notification of a tampered certificate, through mail or by phone to the USDA's Office of General Counsel (OGC).

4. Describe efforts to identify duplication. Show specifically why any similar information already available cannot be used or modified for use for the purpose described in item 2 above.

APHIS is the only Federal agency responsible for preventing the spread of certain animal export diseases from the United States.

5. If the collection of information impacts small businesses or other small entities, describe any methods used to minimize burden.

The information collected is the minimum needed to officially certify, to the satisfaction of receiving countries, that the United States is free of certain animal diseases. APHIS estimates that 60 percent of the respondents are small entities.

6. Describe the consequence to Federal program or policy activities if the collection is not conducted or is conducted less frequently, as well as any technical or legal obstacles to reducing burden.

If the information was collected less frequently or not collected at all, many countries would not accept animal products from the United States, creating a serious trade imbalance and adversely affecting United States exporters.

7. Explain any special circumstances that require the collection to be conducted in a manner inconsistent with the general information collection guidelines in 5 CFR 1320.5.

- **requiring respondents to submit more than an original and two copies of any document;**
- **requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;**
- **in connection with a statistical survey, that is not designed to produce valid and reliable results that can be generalized to the universe of study;**
- **requiring the use of a statistical data classification that has not been reviewed and approved by OMB;**
- **that includes a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or**
- **requiring respondents to submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.**

No special circumstances exist that would require this collection to be conducted in a manner inconsistent with the general information collection guidelines in 5 CFR 1320.5.

8. Describe efforts to consult with persons outside the agency to obtain their views on the availability of data, frequency of collection, the clarity of instructions and recordkeeping,

disclosure, or reporting form, and on the data elements to be recorded, disclosed, or reported. If applicable, provide a copy and identify the date and page number of publication in the Federal Register of the agency's notice, soliciting comments on the information collection prior to submission to OMB.

In 2013, APHIS engaged in productive consultations with the following individuals concerning the information collection activities associated with this program:

Sarah Ewertz
Export Compliance Support
Cargill Meat Solutions
151 N. Main Street
Wichita, KS 67202
Phone: 316-291-3446
Fax: 316-261-3598
Sarah_Ewertz@cargill.com

Beth Kwast
JBS
1770 Promontory Circle
Greeley, CO 80634
Phone: 970-506-7830
Fax: 970-534-2147
Beth.kwas@jbssa.cocm

Steve Doelger
Sigma-Aldrich/SAFC Biosciences
3050 Spruce
St. Louis, MO 63103
Phone: 314-289-6028
Steve.Doelger@sial.com

On Monday, June 14, 2013, pages 37778-37779, APHIS published in the Federal Register, a 60-day notice seeking public comments on its plans to request a 3-year renewal of this collection of information. No comments from the public were received.

9. Explain any decision to provide any payment or gift to respondents, other than reenumeration of contractors or grantees.

This information collection activity involves no payments or gifts to respondents.

10. Describe any assurance of confidentiality provided to respondents and the basis for the assurance in statute, regulation, or agency policy.

No additional assurance of confidentiality is provided with this information collection. Any and all information obtained in this collection shall not be disclosed except in accordance with 5 U.S.C. 552a.

11. Provide additional justification for any questions of a sensitive nature, such as sexual behavior or attitudes, religious beliefs, and other matters that are commonly considered private. This justification should include the reasons why the agency considers the questions necessary, the specific uses to be made of the information, the explanation to be given to persons from whom the information is requested, and any steps to be taken to obtain their consent.

This information collection activity will ask no questions of a personal or sensitive nature.

12. Provide estimates of the hour burden of the collection of information. Indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated.

• Indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated. If this request for approval covers more than one form, provide separate hour burden estimates for each form and aggregate the hour burdens in Item 13 of OMB Form 83-I.

See APHIS Form 71. Burden estimates were developed from discussions with U.S. exporters of animal products.

• Provide estimates of annualized cost to respondents for the hour burdens for collections of information, identifying and using appropriate wage rate categories.

The annualized cost to the above respondents ($1,534,296.90) was calculated by multiplying their estimated average hourly wage ($26.86) (buyers and purchasing agents, farm products) by the number of hours (57,122). The hourly rate is derived from the U.S. Department of Labor; Bureau of Statistics May 2012 Report - Occupational Employment and Wages in the United States. See http://www.bls.gov/news.release/pdf/ocwage.pdf .

13. Provide estimates of the total annual cost burden to respondents or recordkeepers resulting from the collection of information (do not include the cost of any hour burden shown in items 12 and 14). The cost estimates should be split into two components: (a) a

total capital and start-up cost component annualized over its expected useful life; and (b) a total operation and maintenance and purchase of services component.

No annual cost burden is associated with capital and startup costs, operation and maintenance expenditures, and purchase of services.

14. Provide estimates of annualized cost to the Federal government. Provide a description of the method used to estimate cost and any other expense that would not have been incurred without this collection of information.

The annualized cost to the Federal Government is estimated at $1,978,500.46.
(See APHIS Form 79.)

15. Explain the reasons for any program changes or adjustments reported in Items 13 or 14 of the OMB Form 83-1.

ICR Summary of Burden:

	Requested	Program Change Due to New Statute	Program Change Due to Agency Discretion	Change Due to Adjustment in Agency Estimate	Change Due to Potential Violation of the PRA	Previously Approved
Annual Number of Responses	178,502	0	0	44,850	0	133,652
Annual Time Burden (Hr)	57,122	0	0	-9,144	0	66,266
Annual Cost Burden ($)	0	0	0	0	0	0

There is an adjustment increase of +9,000 respondents (from 33,000 in the last submission to 42,000 in this renewal), 44,850 annual responses (from 133,652 to 178,502), and 19,416 hours (from 66,266 to 85,682). The increase in the number of respondents and responses was caused by market forces promoting increased exports. However, APHIS has also recalculated the time required to complete Form VS 16-4, reducing the time per response from 30 minutes to 20 minutes. This resulted in reduced burden of 28,560 hours (84,000 minus 55,440). This was changed after APHIS interviewed the respondents about the time needed to complete the form. In total, therefore, there is a decrease of -9,144 hours (66,266 minus 57,122).

16. For collections of information whose results are planned to be published, outline plans for tabulation and publication.

APHIS has no plans to publish information it collects in connection with this program.

17. If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reasons that display would be inappropriate.

Not applicable. APHIS will display the expiration date.

18. Explain each exception to the certification statement identified in "Certification for Paperwork Reduction Act."

APHIS can certify compliance with all provisions of the Act.

B. Collections of Information Employing Statistical Methods

There are no statistical methods associated with the information collection activities used in this program.